

From:LUCAS & MERCANTI, LLP

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07/07/2006 16:49 #023 P.011/021

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REMARKS

Request for a 2-month Extension of Time for Answering

Applicants hereby request for a 2-month Extension of Time for responding to the outstanding office action. PTO form 2038 is enclosed to authorize the charge for the proper extension fee.

Request for Reconsideration

Applicants have carefully considered the matters raised by the Examiner in the Office Communication but remain of the opinion that patentable subject matter is present. Applicants respectfully request reconsideration of the Examiner's position based on the amended claims and the following remarks.

Claim Status and Amendments

Claims 28-32, 34-44 and 47-55 are now pending and under consideration. Claims 31, 34, 38, 42, 43, 47, and 55 have been amended. Claim 33 has been canceled and its dependent claim 34 has been amended into independent claim.

As discussed in the following sections, most of these amendments are made to clarify the ambiguities raised by the Examiner. Other amendments further narrow the claims in a more restricted way. Hence, all the amendments have their respective support in the previously presented claim set. No new matters have been added.

Claim Objections

Claims 52-53 had been objected to under 37 CFR 1.75(c) as being in improper dependent claim form.

Claim 52 has been amended to refer to other claims in the alternative way by changing "and" into "or". Hence, Claim 52 and its dependent claim 53 are in proper claim format.

Claim Rejections - 35 USC §112

1. Definiteness of the term "specific"

Claims 28-44, 47-51, and 54-55 had been rejected under 35 U.S.C. 112, second paragraph, as being indefinite over

the recitation of the term "specific" in the claims. The applicants respectfully disagree.

The origin of the term "specific" is "species". It is well known by the one skilled in the art that "specific" means "pertaining to a species", "produces by a single kind of microorganism" (see [www.biology-online.org/dictionary/Specific](http://www.biology-online.org/dictionary/Specific)). "characteristic of a defined biological species" (see [www.granddictionnaire.com](http://www.granddictionnaire.com)). Moreover, this term in the claims does not limit the structural and/or functional properties of the nucleic acids which are already precisely defined by their sequence.

It is respectfully submitted that the claim language "specific" is definite and it particularly point out and distinctly claim the subject matter which applicant regards as the invention.

## 2. Regarding Claims 31-32

Claims 31-32 had been rejected as indefinite over the recitation of the phrase "a nucleic acid sequence of claim 28". Claims 31-32 have been amended to specifically recite the sequences, therefore, have been made definite.

3. Regarding Claims 33 - 34

Claim 34 had been rejected as indefinite because of claim 33 from which it depended. Claim 33 has been cancelled and claim 34 has been amended into independent claim. Claim 34 as amended is definite.

4. Regarding Claims 42-44, 47-51, and 54-55

Claims 42-44, 47-51, and 54-55 had been rejected as indefinite as lacking of sufficient antecedent basis for the limitations "the nucleotide sequence...", "the senX3-regX3 region...", "the 3' of senX3 region," and the 5' of regX3 region" in the claims 42, 47, 54, and 55.

Claims 42, 47, 54, and 55 have been amended to change those limitation's article "the" into "a", and thereby removes the need of an antecedent basis.

Regarding claim 43, applicants have amended it by reciting "A nucleotide primer pair of claim 42 consisting of nucleotide primers comprising 19 nucleotides." It is clear that each primer of the pair of claim 42 must

comprise 19 nucleotides. Therefore, Claim 43, as a proper dependent claim, further limits the claim 42, from which it depends.

Regarding claims 47-51, applicants have amended Claim 47 to clarify that the claims are drawn to a method for detection a strain "of *M. tuberculosis* complex."

With further regard to claims 47-51, the relationship between steps 2-3 of claim 47 is clear as currently amended. It is logical that step (3) in claims 47-51 involves the "biological sample" as a result of step (2), so that the sample consists of the biological sample of step (1) containing the amplified sequences.

Regarding claim 55, applicants have amended "the specific nucleic acids" to "the specific nucleotide sequence", which refers to "a specific nucleotide sequence" recited in step (1). Applicants respectfully point it out that "the biological sample" at the beginning of the step (1) refers to "a biological sample" in the preamble of the claim. Hence, sufficient antecedent basis are presented for these limitations in the claim.

Further to Claim 55, applicants have amended it to clarify that the claim 55 is drawn to a method "of detection and of differential diagnosis of BCG and the members of *M. tuberculosis* complex" as set forth in the preamble of the claim.

By amending the step (5) of claim 55 as: "... the presence of said second hybridization complexes being indicative of the presence of a *M. tuberculosis* strain different from BCG and the presence of said first hybridization complexes uniquely being indicative of the BCG", it is clear that a strain might be identified as being BCG by the presence of first hybridization complexes.

Similar with Claim 47, Claim 55 has also been amended to clarify that step 3 to be performed using "the biological sample as a result of step (2)", so that the sample consists of the biological sample of step (1) containing the amplified sequences.

In addition, Claim 55 has been further amended to clarify the indefiniteness. Claim 55 as amended recites the limitation "comprising a region of sequence SEQ ID No: 2

comprising the GAG codon in positions 40 to 42 or the complement of said region". This recitation is definite.

Claim Rejections - 35 USC § 102

Claims 33, 37, and 42-43 had been rejected under 35 U.S.C. 102(e) as being anticipated by Stover et al.

Please note that claim 33 has been cancelled, and the term "comprises" has been replaced by "consists of" in claims 37, 42 and 43.

Regarding claim 37, Stover does not teach a primer or probe consists of a region of SEQ ID NO: 2 comprising the GAG codon (positions 40 to 42) or a complement thereof, as in the amended claim 37.

Claims 42-43 as amended use "consists of" or "consisting of" to restrict the claims to "...one primer consists of a nucleotide sequence of sequences adjacent to a senX3-regX3 region in a 3' of senX3 region and the other primer consist of a nucleotide sequence of sequences adjacent to a senX3-regX3 region in a 5' of regX3 region." No primer or probe disclosed in Stover consists of a

nucleotide sequence adjacent to the SenX3-RegX3 region or a complement thereof. Therefore, claim 42 can not be anticipated by Stover. Accordingly, its dependent claim 43 can not be anticipated either, even though the SEQ ID NO: 11 of Stover is 19 base pairs in length.

It is respectfully submitted that claims 37, and 42-43 are not anticipated by Stover.

Claim Rejections - 35 USC § 103

Claim 54 had been rejected under 35 U.S.C. 103(a) as being unpatentable over Stover in view of Ahem.

The Examiner holds that claim 54 is sufficiently broad to encompass any primer pair with the primers comprise any sequence of any length located outside the "senX3-regX3" region, and accordingly, the primer pairs of Stover are sufficient to meet the requirements of the claims.

Claim 54 has been amended by replacing "comprising" by "consisting of". Thus, the object of claim 54 is a primer pair, one adjacent to the senX3-regX3 region in the 3' of senX3 region and the other adjacent to the senX3-regX3

region in the 5' of regX3 region, specific for amplification of the senX3-regX3 region. No document in the art suggested that the senX3-regX3 region contains a sequence absent in BCG which provides a means to differentiate BCG and the other strains of *M. tuberculosis* complex. The primer pairs of Stover do not consist of sequences adjacent to the senX3-regX3 region and have been designed to amplify a selected deletion junction sequence which is specific to the avirulent BCG strain of *Mycobacterium bovis*.

Therefore, Stover does not teach a primer pair in which one adjacent to the senX3-regX3 region in the 3' of senX3 region and the other adjacent to the senX3-regX3 region in the 5' of regX3 region. Ahern does not teach this primer pair either. The combination of Stover and Ahern does not remedy this lack of teaching.

It is respectfully submitted that Claim 54 can not be rendered obvious by the teaching of Stover and Ahern, and it is patentable over Stover in view of Ahern.

Conclusion

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07/07/2006 16:51 #023 P.020/021

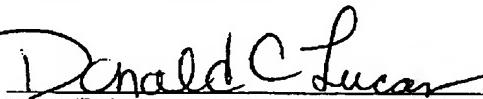
In view of the foregoing, it is respectfully submitted that the Application is in condition for allowance, and this action is respectfully requested.

Should any extensions of time or fees be necessary in order to maintain this Application in pending condition, appropriate requests are hereby made and authorization is given to debit account # 02-2275.

Respectfully submitted,

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Enclosure: PTO-2038